



CERTIFICATE

EC Certificate No. 1434-MDD-225/2020

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

ChM sp. z o.o.

Lewickie 3B,

16-061 Juchnowiec Kościelny

Poland

for the design, manufacture and final inspection of
medical devices, class III

RESORBABLE MICROSYSTEMS FOR MIXILLOFACIAL SURGERY

The list of medical devices covered by this certificate is provided in the Annex 1, 2 and 3 to EC Design-examination Certificate No. 1434-MDD-224/2020

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.05.2020 to 27.05.2024

The date of issue of the Certificate: 21.05.2020

The date of the first issue of the Certificate: 05.12.2017



Issued under the Contract No. **MD-27/2017**
Application No: **375/2019**
Certificate bears the qualified signature.
Warsaw, 21/05/2020
Module H2/3/4/5

Anna
Małgorzata
Wyroba
Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.05.28
14:11:24 +02'00'
mgr Anna Wyroba
Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-224/2020

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

ChM sp. z o.o.

Lewickie 3B,

16-061 Juchnowiec Kościelny

Poland

related to the medical device, class III

RESORBABLE MICROSYSTEMS FOR MIXILLOFACIAL SURGERY

The list of medical devices covered by this certificate is provided in the Annex 1, 2 and 3

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.05.2020 to 27.05.2024

The date of issue of the Certificate: 21.05.2020

The date of the first issue of the Certificate: 05.12.2017



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Application No: **375/2019**

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Warsaw, 21/05/2020

Module H1

Anna
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Wyroba
mgr Anna Wyroba
Vice-President

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Małgorzata Wyroba
Data: 2020.05.28
14:09:11 +02'00'



ANNEX NO. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No. 1434-MDD-224/2020

List of medical devices covered by the certificate:

REF	REF	Name
BIOABSORBABLE SCREWS		
6.0006.003	6.3006.003	Cortical bioabsorbable screw 1.5x3
6.0006.004	6.3006.004	Cortical bioabsorbable screw 1.5x4
6.0006.005	6.3006.005	Cortical bioabsorbable screw 1.5x5
6.0006.006	6.3006.006	Cortical bioabsorbable screw 1.5x6
6.0006.008	6.3006.008	Cortical bioabsorbable screw 1.5x8
6.0007.004	6.3007.004	Cortical bioabsorbable screw 2.0x4
6.0007.006	6.3007.006	Cortical bioabsorbable screw 2.0x6
6.0007.008	6.3007.008	Cortical bioabsorbable screw 2.0x8
6.0007.010	6.3007.010	Cortical bioabsorbable screw 2.0x10
6.0008.004	6.3008.004	Cortical bioabsorbable screw 2.5x4
6.0008.006	6.3008.006	Cortical bioabsorbable screw 2.5x6
6.0008.008	6.3008.008	Cortical bioabsorbable screw 2.5x8
6.0008.010	6.3008.010	Cortical bioabsorbable screw 2.5x10



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Vice-President

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Małgorzata Wyroba
Data: 2020.05.26
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ANNEX No. 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-224/2020

List of medical devices covered by the certificate:

REF	REF	Name
BIOABSORBABLE PLATES		
6.0010.008	6.3010.008	Scalloped adaptation plate 8 holes
6.0010.020	6.3010.020	Scalloped adaptation plate 20 holes
6.0011.002	6.3011.002	Straight plate 2 holes
6.0011.004	6.3011.004	Straight plate 4 holes
6.0012.008	6.3012.008	Adaptation plate 8 holes
6.0012.020	6.3012.020	Adaptation plate 20 holes
6.0013.210	6.3013.210	Scalloped strut plate 2x10 holes
6.0013.218	6.3013.218	Scalloped strut plate 2x18 holes
6.0013.236	6.3013.236	Scalloped strut plate 2x36 holes
6.0014.210	6.3014.210	Strut plate 2x10 holes
6.0014.218	6.3014.218	Strut plate 2x18 holes
6.0014.236	6.3014.236	Strut plate 2x36 holes
6.0015.005	6.3015.005	T-Plate 2x3 holes
6.0016.010	6.3016.010	C-Plate 10 holes
6.0017.010	6.3017.010	Double Y-Plate 10 holes
6.0018.004	6.3018.004	X-Plate 4 holes
6.0018.008	6.3018.008	X-Plate 8 holes
6.0019.010	6.3019.010	Y-Plate 4x3x3 holes
6.0020.024	6.3020.024	Orbital plate
6.0020.030	6.3020.030	Orbital plate
6.0020.035	6.3020.035	Orbital plate
6.0021.008	6.3021.008	Burr hole cover plate 8 holes
6.0021.010	6.3021.010	Burr hole cover plate 10 holes



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ANNEX No. 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-224/2020

List of medical devices covered by the certificate:

REF	REF	Name
BIOABSORBABLE PLATES		
6.0022.001	6.3022.001	Sellar floor plate
6.0022.002	6.3022.002	Sellar floor plate
6.0023.004	6.3023.004	Box plate
6.0024.002	6.3024.002	Straight plate 2 holes
6.0024.004	6.3024.004	Straight plate 4 holes elongated
6.0025.008	6.3025.008	Adaption plate 8 holes
6.0025.020	6.3025.020	Adaption plate 20 holes
6.0026.210	6.3026.210	Strut plate 2x10 holes
6.0026.218	6.3026.218	Strut plate 2x18 holes
6.0026.236	6.3026.236	Strut plate 2x36 holes
6.0027.010	6.3027.010	Y-Plate 4x3x3 holes
6.0028.010	6.3028.010	Oblique L-Plate right 6x4 holes
6.0029.010	6.3029.010	Oblique L-Plate left 6x4 holes
6.0030.010	6.3030.010	C-Plate 10 holes
6.0110.025	6.3110.025	Mesh plate 0.8/25x25
6.0110.050	6.3110.050	Mesh plate 0.8/50x50
6.0124.025	6.3124.025	Mesh plate 1.2/25x25
6.0124.050	6.3124.050	Mesh plate 1.2/50x50
6.0130.012	6.3130.012	Round plate 1,2/12
6.0130.017	6.3130.017	Round plate 1,2/17
6.0130.022	6.3130.022	Round plate 1,2/22



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15:12:56 +02'00'

mgr Anna Wyroba
Vice-President